Docket No. MCP-5021

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

plicants : David W. Wynn et al.

Serial No.: 10/697,840

Art Unit:

Filed

Examiner:

: October 30, 2003

: CONTROLLED RELEASE ANALGESIC SUSPENSIONS For

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Dear Sir:

Pursuant to 37 C.F.R. \$1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the aboveidentified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

| ☑ In accordance with §1.97(b), since this Information |
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| Disclosure Statement is being filed either within three months |
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| (other than a continued prosecution application under |
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| national stage of the above identified application as set forth |
| in §1.491, or before the mailing date of a first Office Action $$ |
| on the merits of the above-identified application, or before |
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| In accordance with §1.129(a), this Information |
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| (attached); or |
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| (a)(2). (The U.S. patents and each U.S. patent application |

publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i).

- \boxtimes There are no listed references which are not in the English language.
- ☐ The relevance of those listed references which are not in the English language is as follows:
- Attached are copies of search report(s) from related PCT Patent Application No. PCT/US03/08846 (Atty. Docket MCP-325 PCT), which is listed on the attached Submission Under MPEP 609D.
- Attached are the non-published pending patent
 Application Nos. 10/697,546 (Atty. Docket MCP-5015) and
 10/393,755 (Atty. Docket MCP-325), which may be deemed relevant
 and are listed on the attached Submission Under MPEP 609D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/MCP5021/MGM. This form is submitted in triplicate.

Respectfully submitted,

Michele 0. Mangini Reg. No 36,806 Attorney for Applicants

Johnson & Johnson Plaza One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-2810 DATED: 9 FW 2004

SUBMISSION DER MPEP 609 D

| Application Number | 10/697,840 |
|------------------------|------------------|
| Filing Date | October 30, 2003 |
| First Named Inventor | Wynn et al. |
| Group Art Unit | |
| Examiner Name | |
| Attorney Docket Number | MCP-5021 |

Page 1 of 1

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| /C.B./ | | McNEIL-PPC, Inc. | 10/393,755 | (Atty. Docket I | MCP-325) | | 21 | |
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| 70.6.7 | | PCT Search Report dated October 6, | ,2003 for PCT/ | US03/08846 (| Atty. Docket I | MCP-325) | | |
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Application Included Interest of Section 1 (1997), 840

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| Examiner Initials | Cita No. | Offica ³ | Number ⁴ Ki | ndCode ⁵ | Applicant of Cited Document | mm-dd-yyyy | passages or relevant figures appear |
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| Examiner /Courtney Brown/ | Date Considered | 12/20/2008 |
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Application Number 10/697,840 INFORMATION DISCLOSURE Filing Date October 30, 2003 FIRST Named Inventor Group Art Unit Examiner Name

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| Examiner 100 to the | Date 12/20/2008 · |
|----------------------------|-------------------|
| Signature /Courtney Brown/ | Considered |
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Application Number 10/697,840 October 30, 2003 Filing Date INFORMATION DISCLOSURE First Named Inventor Wynn et al. Group Art Unit STATEMENT BY APPLICANT Examiner Name MCP-5021

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item Cite Examiner's (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published Arneer, B., et al., Ann. Int. Med. 82, pp. 202-209 (1977) Initials* No.1 /C.B. USP 23 (1995) pp. 786 USP 24, 2000 Version, 19-20 and 856-857 (1999) Lieberman, Herbert A. and Lachman, Leon, 'Pharmaceutical Dosage Forms: Tablets, Volume 3, pp. 73-117 and 119-221 Setty, Chitrali et al., "Development and in vito evaluation of multiparticulate sustained release formulation of diffizem hydrochloride using ethylocitulose and cellulose acetate phthalate," Indian Drugs 35(4) April 1998, pp. 195-199 Walter, K., et al., "Pharmacokinetics of ibuprolen following a single administration of a suspension containing enturic coated microcapsules." Azneim-Forsch/ Drug Res. 45 (II), Nr. 8 (1995), pp. 888-890 Kurumaddal, K.R. et al., "Preparation and evaluation of sustained release ibuprofen beads," Drug Development and Industrial Pharmacy, 20(17), (1994) pp. 2659-2669 BELLAMY N. (Reprint) ET. AL: "A comparative-enalysis of two dosing strategies of Flurbiprofen in Rheumatoid-Arthrits-An Application of Sequential Trial Design" Clinical and Investigative Medicine-Medecine Clinique ET Experimentale, (1988) Vol. 11, No. 6, Pt. 441-445., XP00901716 BLACK, P. ET. AL: "A randomized, double-blind, placebo-controlled comparison of the analgesic efficacy, onset of action, and blerability of ibuprofen arginate and buprofen in postoperative dental pain" CLINICAL THERAPEUTICS, Vol. 24, No. 7, 2002, pages 1072-1089, XP002254117 GREBE, W. ET. AL: "A multicenter, randomized, double-blind, double-dummy, placebo-and active-controlled, parallel-group comparison of dictofenac-K and buprofen for the treatment of adults with influenza-like symptoms." CLINICAL THERAPELTICS, Vol. 25, No. 2, February 2033 (2003-02), pages 444-458, XP001155030 MEHLISCH, D.R.: "Ketoprofen, ibuprofen and placebo in the treatment of primary dysmenorrhea: a double-blind crossover comparison" J. Clin Pharmacol., Vol. 29, No.12, December 1988 (1988-12), pages \$29-33, XP009017179 MEHLISCH, D.R.: "Double-blind crossover comparison of ketoprofen, naproxen, and placebo patients with primary dysmenorrhea" CLINICAL THERAPEUTICS, Vol 12, No 5, 1990, pages 398-409, XP009017199 PALMISANO, G. P. ET AL: * Double-blind crossover comparison of ketroprofen, itsuprofen, and placebo in the treatment of patients with primary dysmanomhea* ADVANCES IN THERAPY, VOL. 5, NO. 4, 1988, pages 128-137 XP009017375

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